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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,706	09/24/2001	William E. Munger	044921-5029-01	4547
9629	7590	10/06/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/960,706		MUNGER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Marjorie A. Moran		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-38, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38 and 55-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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All objections and rejections not reiterated below are hereby withdrawn.  
Claims 32-38 and 55-56 are pending.

***Information Disclosure Statement***

It is noted that in the response filed 7/16/04, applicant states on page 5 that replacement copies of references cited in the IDS's of 6/11/02 and 8/21/02 "have been supplied." No such copies have been received by the office and the filing papers of 7/16/04 do not indicate that any references were included with the filing of the amendment and arguments. The examiner again regrets the inconvenience and requests that applicant submit another copy of each non-patent reference. The date of filing of any reference previously cited will be considered the date of filing of the original IDS.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup>***

Amended claims 32-38 and new claims 55-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A computer system comprising a database containing information concerning expression levels of "at least ten" or "at least 50" or "at least 70" different nucleic acid molecules is new matter. In addition, a computer system

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comprising software for comparing a sample to information in the database is new matter.

Original claims 28-31, directed to a solid support comprising oligonucleotide probes, limited an array to comprise 10, 100, 1000, or 10,000 different oligonucleotides. Claims directed to an array of physical oligonucleotides do not provide support for a computer system comprising database of sequence information. Original claims 32 and 33, directed to a computer system, limited a database to comprise "at least two" genes. Nowhere did the original claims recite a database comprising sequence information for "at least ten", "at least 50" or "at least 70" different nucleic acid molecules.

The originally filed specification, on page 7, discloses an array comprising oligonucleotides which hybridize to at least 2, 3, 4, 5, 6, 7, 8, 9, 10, 10, 30, 50, or 70 genes described in Tables 1-6. An oligonucleotide which hybridizes to a sequence is not the same as the nucleic acid sequence described, nor even necessarily an exact complement thereof, as the hybridizing sequence may be shorted, longer, have single or multiple gaps, etc. Further, as set forth above, an array comprising physical oligonucleotides is not support for a database comprising sequence information. The originally filed specification does disclose a database on page 15, but again, only specifically discloses that the database contains information with regard to expression of "at least two" genes in a Table. Nowhere do the originally filed specification or claims provide support for a database containing expression information for at least ten, 50, or 70 different nucleic acid molecules.

Amended claim 1 now limits a computer system to comprise software “that allows a user to compare data from a sample to data in the database.” The original claims did not recite software. Original claim 1 recited a user interface; as a user interface may be no more than a monitor screen or disk drive or other input/output device, the user interface of original claim 1 is not support for software which is capable of “allowing” specific functions. The originally filed specification, on page 15, discloses that “any appropriate computer platform” may be used to perform comparisons between various kinds of information. Page 15 further discloses that client/server environments, database servers, and networks are “appropriate” platforms. None of these are specific support for a computer system comprising SOFTWARE (i.e. a program) for comparing a sample to information in a database. The specification is silent with regard to any specific program, set of computer-implemented instructions, etc., which may be interpreted as software, in the inventive database. No program for sequence comparison is disclosed. While programs for sequence comparison are known in the art, applicant is reminded that a disclosure by the prior art is not sufficient to provide a full and complete written description of *applicant's* invention.

Applicant does not point to support for the newly filed limitations and none is apparent, as set forth above, therefore the claims are rejected for reciting new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-38 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over MASLYN et al. (US 5,953,727)

MASLYN teaches a computer system comprising relational sequence information (col. 2) and software for allowing a user to compare query (sample) data to data in the database (col. 3, lines 4-10). It is noted that as the sequence and data expression level information recited in the claims do not have a functional relationship with the hardware recited in the claims, they do not

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distinguish the invention from the prior art in terms of patentability. The sequences and associated information are nonfunctional descriptive matter (see MPEP 2106), and do not *functionally* interact with the computer system itself; i.e. the sequences are not changed or transformed by the system or software nor is the computer system itself changed or transformed. The claimed software may be used with any set of oligonucleotide information without affecting the computer system itself. As set forth in *In re Gulack*, 703 F. 2d 1381 (217 USPQ 403,404), when there is no functional relationship between matter which is, by itself, non-statutory subject matter and a substrate (e.g. a computer), there is no reason to give patentable weight to the content (of the non-statutory subject matter). The oligonucleotides recited in the claims do not therefore distinguish the claimed system from the prior art in terms of patentability, and the claims are obvious.

Applicant's arguments filed 7/16/04 have been fully considered but they are not persuasive. Applicant argues that the software functionally links the oligonucleotide information to "the ability of a user" to compare sample information to the information in the database. The claimed software may be used with any set of oligonucleotide information without affecting the data or computer system itself. Thus, the software does not functionally interact with the data. As the prior art teaches software for comparing sample information to data in a database, as set forth above, neither the data itself nor the software distinguish the claims from the prior art, and the rejection is maintained.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
9/30/04